

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ICAHN SCHOOL OF MEDICINE AT
MOUNT SINAI,

Plaintiff,

v.

NEUROCRINE BIOSCIENCES, INC.,

Defendant.

15 Civ. 09414 (RWS)

Judge: Hon. Robert W. Sweet

Oral Argument Date:
March 17, 2016 at 12:00 p.m.

**REPLY IN SUPPORT OF MOTION TO DISMISS BY
DEFENDANT NEUROCRINE BIOSCIENCES, INC.**

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I. INTRODUCTION

Mt. Sinai contends that, at the time the Mt. Sinai license agreement was signed, both parties contemplated that Neurocrine would use Mt. Sinai's patented drug-discovery tool to discover potential compounds, spend years and untold sums to develop a compound and then, nearly a decade later, go back to Mt. Sinai to ask how much money Mt. Sinai wants. No person in his right mind would consent to such an arrangement, and the parties here certainly never did.

To the contrary, the plain text of the two contracts at issue forecloses Mt. Sinai's claim. Under the Mt. Sinai license, Neurocrine agreed to seek Mt. Sinai's permission only if it wanted to grant a sublicense "under the License"—i.e., to the "patent and the patent applications" listed in an exhibit. Ex. 2 at § 2.1(c). Neurocrine has never sublicensed such rights. Just the opposite, the Collaboration Agreement between Neurocrine and AbbVie [REDACTED]

[REDACTED] Because there is no possible overlap between what Mt. Sinai granted to Neurocrine and what Neurocrine granted to AbbVie, Neurocrine did not grant an impermissible sublicense as a matter of law.

To obfuscate this straightforward conclusion, Mt. Sinai's opposition brief tries to confuse the record by (1) pointing to isolated, out-of-context snippets from both agreements, (2) relying on extrinsic evidence to contradict the agreement's terms, and (3) making wholly conclusory accusations that, regardless of what the contract says, AbbVie and Neurocrine are essentially conspiring to give AbbVie back-door access to Mt. Sinai's drug-discovery tools, despite that there are absolutely no well-pled facts even hinting that such a conspiracy occurred. Mt. Sinai even goes so far as to submit an impermissible, "Hail Mary" declaration from its purported expert who claims that in the academic licensing context, agreements do not mean what they say. When all this dust is cleared, however, the fact remains: Neurocrine has not granted any sublicense to AbbVie, and nothing in the complaint, the contracts, or the supplemental materials Mt. Sinai submitted to salvage its defective pleading suggests otherwise.

Neurocrine did not sublicense the rights it received from Mt. Sinai to AbbVie, and Mt.

Sinai fails to adequately allege breach or damages from Neurocrine's alleged failure to provide timely development reports or the unredacted AbbVie agreement. Dismissal is proper.

II. ARGUMENT

A. Neurocrine Did Not Sublicense Mt. Sinai's Patents To AbbVie

1. Mt. Sinai Cannot Avoid The Collaboration Agreement's Express Disavowal Of Any Sublicense By Dismissing That Clause As "Artful Wording"

Under the Mt. Sinai license, Mt. Sinai did not license anything to Neurocrine other than its patents to the drug-discovery tools. *See* Part II.A.2.b., *infra*. By the plain terms of the AbbVie Collaboration Agreement, however, Neurocrine transferred only the patents on Exhibit C; Mt. Sinai's patents are not on that list, and Mt. Sinai does not claim otherwise. *See* Mot. at 3–4. Further, the Agreement explicitly states that the technology that Neurocrine is contributing to the collaboration [REDACTED]

[REDACTED] *See id.*

To avoid dismissal, however, Mt. Sinai asks the Court to ignore this damaging fact as mere "artful wording," and instead examine the "actual" relationship between the parties. *See* Opp'n at 10. But that examination reveals simply that Neurocrine and AbbVie agreed to work together to develop and commercialize Elagolix, and further agreed that AbbVie would have no rights to the Mt. Sinai drug-discovery tools to ensure there would be no impermissible sublicense. *See* Exs. 3, 5. There is nothing untoward about the relationship between Neurocrine and AbbVie, and there is nothing in the Mt. Sinai license that prevents or restricts Neurocrine's ability to collaborate with a pharmaceutical partner to jointly develop and commercialize a drug candidate in this manner—even one discovered by Neurocrine utilizing the licensed patents.

To argue otherwise, Mt. Sinai relies on *E.I. Du Pont v. Shell Oil Co.* 498 A.2d 1108 (Del. 1985), a case in which a court found an impermissible sublicense. Opp'n at 10. There, after Carbide was unable to get a license from Du Pont, it set up a sham transaction with one of Du Pont's existing licensees, Shell. *Du Pont*, 498 A.2d at 1110. Through that arrangement, Carbide agreed to manufacture the patented articles "for Shell" and then immediately buy them back; in

other words, Carbide made and sold the patented articles completely on its own, despite claiming not to have a sublicense. *Id.* The court disagreed, explaining that there was no purpose for the arrangement other than to circumvent the sublicensing restriction. *Id.* at 1111–17.

Here, however, there are no allegations that would support a plausible inference that the Collaboration Agreement is a “sham” transaction arranged solely to convey an impermissible sublicense. To the contrary, Neurocrine’s agreement with AbbVie is a legitimate, bona fide collaboration replete with ongoing rights and obligations completely separate and apart from any possible use of Mt. Sinai’s patents by either party.¹ Compare, e.g., *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 48–49 (Fed. Cir. 2012) (distinguishing *Du Pont* and finding no impermissible sublicense where arrangement was “bona fide”); *Cyrrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1387 (Fed. Cir. 1996); Mot. at 10–14. Further, in direct contrast to *Du Pont* where the entire agreement was set up and performed to let Carbide manufacture and sell the patented product *Du Pont* refused to license, Mt. Sinai does not allege that AbbVie has in fact ever used Mt. Sinai’s patented drug-discovery tool. See Compl. ¶¶ 26–87. Instead, Mt. Sinai argues only that because AbbVie could theoretically ask Neurocrine to use the tools as part of the joint development process, the entire agreement is a sham.² But even if the Collaboration Agreement contemplated some possible use of Mt. Sinai’s patents (which it did not), no facts support an inference that the contract is a “paper transaction” designed to evade sublicensing restrictions.

Indeed, the only “fact” that Mt. Sinai alleges does not support its claim. Specifically, Mt. Sinai argues that (like Carbide in the *Du Pont* case) Neurocrine knew it needed Mt. Sinai’s consent before working with AbbVie because “Neurocrine contacted Mount Sinai after it began

¹ For example, the Collaboration Agreement contains a separate exhibit with a detailed “Collaborative Development Plan” that [REDACTED]

[REDACTED] See Ex. 5 at Ex. G; see also *id.* at Ex. F.

² This argument is further belied by the fact that, under Mt. Sinai’s theory, AbbVie paid a \$75 million upfront fee just to get backdoor access to a license for which Neurocrine paid \$50,000.00. Compare Ex. 5 at § 4.1, with Ex. 2 at § 3.1. This makes no economic sense.

discussions with AbbVie, and acknowledged that Mount Sinai's consent was required." Opp'n at 10; *see also id.* at 6. But as Mt. Sinai admits, this "fact is not alleged in the Complaint." Opp'n at 6 n.2. Further, it is false. Neurocrine contacted Mt. Sinai about a potential sublicense not in relation to its discussions with AbbVie (as the Opposition suggests), but with an entirely *different* company, that (unlike AbbVie) *did* want to use Mt. Sinai's patented technology in connection with its own drug-discovery program to find new compounds, rather than develop and commercialize the compounds Neurocrine identified years earlier.³ Ryan Decl. at ¶ 1, Ex. 6. Neurocrine's good faith effort to get Mt. Sinai's permission during these separate negotiations underscores that the "actual" reason the AbbVie Agreement excludes Mt. Sinai's patents is not to circumvent the restrictions on sublicenses, but because AbbVie didn't need or want one. *Contra* Opp'n at 9. It also shows that Neurocrine was aware of the circumstances where Mt. Sinai's consent was required (sublicensing the patents) and when it was not (licensing only the compounds) and evidences Neurocrine's good faith in asking for a sublicense where (unlike here) one was needed. Mt. Sinai's continued reliance on a purported fact that it knows to be untrue and is outside the Complaint is improper, and demonstrates just how far Mt. Sinai will go to support its legally defective claim.

2. Mt. Sinai's Additional Breach Theories Do Not Save Its Claim

This Court should dismiss the claims based on the Collaboration Agreement's express disavowal of any sublicense alone. Should the Court evaluate Mt. Sinai's additional attempts to circumvent the plain language of the agreements, however, those attempts must also fail.

a. Neurocrine Did Not Transfer Any Mt. Sinai Technology Under The AbbVie Agreement

Mt. Sinai's first theory—that, despite the provision expressly excluding any of Neurocrine's rights under the Mt. Sinai License, Neurocrine implicitly granted AbbVie a sublicense by agreeing to transfer certain technology—is meritless. *Contra* Opp'n at 11–13. Mt.

³ Neurocrine informed Mt. Sinai's in-house counsel of this fact days before the Opposition filing, so it is bizarre that Mt. Sinai would nevertheless make this inaccurate claim to the Court.

Sinai here argues that because the definition of “Technology” is theoretically broad enough to encompass “the Sealfon discovery tools and related cell lines,” Neurocrine’s “agreement to transfer the licensed Sealfon tools for AbbVie’s use results in a sublicense.” *Id.* at 12.

This argument fails. First, the Complaint does not allege that Neurocrine even possessed any “cell lines” or “Sealfon discovery tools” at the time of the Collaboration Agreement in 2010, much less transferred them to AbbVie, meaning that Mt. Sinai’s argument that Neurocrine agreed to transfer these tools is baseless. *See* Compl. ¶¶ 26–87. Second, the Collaboration Agreement plainly states that there are “No Implied Licenses” granted under the Agreement other than the express list of “Neurocrine Patent Rights” contained in Exhibit C, which does not include the Mt. Sinai patents. *See* Ex. 5 at § 3.5. This clause is dispositive. *See, e.g., Endo Pharms., Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1378 (Fed. Cir. 2014) (holding “No Implied Rights” clause controlled). Third, Mt. Sinai’s argument is contrary to the principle that “if there is an inconsistency between a specific provision and a general provision of the contract, the specific provision controls.” *Brady v. Williams Capital Group, L.P.*, 64 A.D.3d 127, 141 (N.Y. App. Div. 2014) (quotation marks and ellipses omitted). Thus, even if the meaning of “technology” in its broadest sense could conceivably include Mt. Sinai’s patents or the raw materials related thereto, the more specific provisions that state that Mt. Sinai’s patent rights are expressly not included in the Collaboration Agreement control.⁴ *See* Ex. 5 at §§ 1.50, 3.5, Ex. C.

b. Neurocrine Did Not License Anything Other Than Mt. Sinai’s Patents To The Drug-Discovery Tool

Mt. Sinai next argues that Neurocrine breached the sublicensing restrictions because the “License” Mt. Sinai granted to Neurocrine included not only the right to use its patents, but the right to develop and commercialize any products discovered using those patents. Opp’n at 13–20. But by its terms, the Mt. Sinai agreement defines the “License” as the “nonexclusive

⁴ To be clear, if Mt. Sinai believes AbbVie is using its cell lines or patented technology that has not yet expired, it is free to sue AbbVie for patent infringement because Neurocrine did not grant or purport to grant any rights to that technology through the Collaboration Agreement. That fact *proves* that AbbVie does not have a sublicense to the Licensed technology.

worldwide license to make and use the subject matter covered under the Licensed Patent Rights,” which were defined as the “valid and issued or pending claims included in . . . the US patent and patent applications listed on the attached Exhibit A.” Ex. 2 at § 1.2. Those patents relate only to drug-discovery tools; the agreement does not purport to grant any license to the yet-to-be-discovered compounds (which makes sense, since Mt. Sinai did not have any patents or rights⁵ over those yet-to-be-discovered compounds to give).⁶ As such, Neurocrine’s license to AbbVie of the compounds it discovered does not constitute an impermissible sublicense of anything it received from Mt. Sinai. Mt. Sinai fights the contract’s definition of “License,” which is plainly limited to its patents, based on (1) unrelated provisions in the agreement, (2) its purported licensing expert’s say-so, and (3) impermissible extrinsic evidence of Neurocrine’s intent as revealed in misleading excerpts of its SEC filings. None of these arguments are persuasive.

Mt. Sinai first attempts to confuse the issue by claiming that the parties “expressly agreed these ‘discovered’ drugs would be ‘Licensed Products.’” Opp’n at 14. But there is no question that Neurocrine never licensed Elagolix or any drug compound from Mt. Sinai; instead, “Licensed Products” was merely the nomenclature the parties used to describe the compounds Neurocrine identified using the drug-discovery tools. *See* Ex. 2. Further, Neurocrine’s only

⁵ In truth, no one had any rights to these compounds yet, as they had not yet been invented. But when they were invented, the IP belonged exclusively to Neurocrine. We know this because nothing in the Mt. Sinai license gives Mt. Sinai rights to future IP created out of the performance of the Agreement, which is what the contract would have said had the parties so intended. *See, e.g., Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 361 F. Supp. 2d 210, 215 (S.D.N.Y. 2005). Further, Neurocrine owns all the patents to Elagolix, *see* Ex. 5 at Ex. C, and Mt. Sinai has never challenged ownership of those patents.

⁶ Mt. Sinai admits that it is “stat[ing] the obvious” to say that “[a party] cannot convey . . . any more than the rights it ha[s].” Opp’n at 16 n.5. Yet Mt. Sinai also claims that “a license can extend to drugs that [a]re discovered using licensed drug discovery tools” even where the patentee holds rights only over the drug-discovery tool, and not over the resulting product. *Id.* To support this novel proposition, Mt. Sinai cites only to *Bayer AG v. Housey Pharm.*, 228 F. Supp. 2d 467, 470 (D. Del. 2002). But there, the court held only that, in some cases, a patentee can tether royalties for the drug-discovery tool to sale of the yet-to-be-discovered compounds; it did not say that the license itself would “extend” to those compounds or that a party could grant “rights” to a compound over which it had no protectable IP interest. Here too, although the parties tethered royalties to the sale of the compounds, nothing suggests that Mt. Sinai intended to convey, or could have conveyed, any rights to those compounds in the license grant.

obligations with respect to the “Licensed Products” were to provide development reports, indemnify Mt. Sinai for product liability claims, and pay a royalty to Mt. Sinai based on sales. Ex. 2 at §§ 3.3, 3.5, 6. Neurocrine has no other obligations regarding the “Licensed Products,” nor are the “Licensed Products” mentioned anywhere in the sublicensing clause. Instead, that clause states only that Neurocrine needed Mt. Sinai’s permission “to grant sublicenses under the License,” which, as described above, is limited to Mt. Sinai’s drug-discovery patents. Ex. 2 at § 2.1(c). Had Mt. Sinai wanted to extend the sublicensing provision to rights “under the License or to the Licensed Products,” the contract could have said so. It does not.⁷

Mt. Sinai’s second argument is that an expansive definition of the term “license” is consistent with custom and practice in the industry, and that its expert’s declaration on this issue at least suffices to render the contract ambiguous. Opp’n at 16. Not so. As courts have explained, “[t]he unambiguous terms of the contract speak for themselves” and so must be construed without resort to extrinsic evidence, including expert testimony. *See Marin v. Const. Realty, LLC*, 128 A.D.3d 505 (N.Y. App. Div. 2015); *see also BOKE v. Caesars Entm’t Corp.*, 2015 U.S. Dist. LEXIS 113794, at *24–25 (S.D.N.Y. 2015). For that reason, even expert testimony on industry terminology is not permissible unless the terms are so hyper-technical that they “convey no meaning” to people outside the field. *Id.* Where language has an everyday meaning, however, expert testimony “concerning custom and practice in the industry” is inadmissible parol evidence. *Katel L.L.C. v. AT&T Corp.*, No. 1:01-cv-02440, 2009 U.S. Dist. LEXIS 29299, at *3–4 & n.1 (S.D.N.Y. Mar. 17, 2009). Courts therefore do not allow parties to

⁷ Mt. Sinai’s attempt to expand the scope of its license by claiming that Neurocrine had the right to use its patents to “identify, screen for and/or develop products” fares no better. Opp’n at 15. Mt. Sinai here argues that because Mt. Sinai granted Neurocrine the right to use its patent to develop products, all “downstream development” is covered by the license. *Id.* But simply because Mt. Sinai granted Neurocrine the right to use its patents for development purposes doesn’t mean that all development is covered by the license, regardless of whether or not the patent is used. In other words, the phrase “to identify, screen for and/or develop” is a *limitation* on the manner in which Neurocrine can use the patents, it is not a grant of any *additional* power beyond what the patents afford. It clarifies, for example, that Neurocrine can only use the patents to identify, screen for, and/or develop products; it cannot use the patents to manufacture the drug-discovery tools for retail sale. Mt. Sinai’s reading of this clause is contrary to its terms.

“introduce the affidavits of [industry] experts . . . to explain away the specific terms of the [agreement] as ambiguous.” *Red Rock Commodities v. Standard Chtd. Bank*, 140 F.3d 420, 423 (2d Cir. 1998). Likewise here, because the term “License” is specifically and unambiguously defined in the Mt. Sinai agreement itself, Mt. Sinai cannot submit the declaration of an industry expert to “explain away the specific terms” in response to Neurocrine’s motion to dismiss.⁸

Third, Mt. Sinai argues that the License is broader than a “pure patent license” by pointing to Neurocrine’s SEC filings. Opp’n at 17. First, such extrinsic evidence is irrelevant because the contract is unambiguous. *Goldman v. White Plains Ctr. for Nursing Care, LLC*, 896 N.E.2d 662, 664 (N.Y. 2008) (“[A] written agreement that is . . . unambiguous on its face must be enforced . . . without reference to extrinsic materials . . .”). Moreover, Mt. Sinai misstates what Neurocrine has said. For example, Mt. Sinai claims Neurocrine recognized that “the Mount Sinai License is one ‘to develop and commercialize licensed products worldwide’” to make it seem like Neurocrine understood the breadth of the contract. Opp’n at 17. But the full quote states that Neurocrine obtained “a nonexclusive license to certain patents and patent applications related to GnRH, to develop and commercialize licensed products worldwide.” Ex. 7 (omitted portion underlined). In context, the “to develop and commercialize” language Mt. Sinai excerpted is a *limitation* on what Neurocrine could do with the patents, not an additional grant of rights. Mt. Sinai cannot crop quote the part saying the only thing Neurocrine received was a “license to certain patents” to argue that Neurocrine itself thought it got something more.⁹

c. Neurocrine Did Not Grant AbbVie A “*De Facto*” Sublicense

In a final attempt to avoid the contracts’ unambiguous terms, Mt. Sinai argues that Neurocrine gave AbbVie a “*de facto*” sublicense by granting AbbVie the right to direct and

⁸ The declaration is further improper for the reasons set forth in the Objections filed herewith.

⁹ Mt. Sinai’s select excerpts of the Collaboration Agreement are also flawed. Here, Mt. Sinai claims AbbVie “insist[ed]” that Neurocrine keep the Mt. Sinai License and uses this allegation to suggest Neurocrine conspired with AbbVie to grant a *de facto* sublicense. See Opp’n at 8, 19, 23. But Mt. Sinai’s theory is based only on a boilerplate representation that Neurocrine would keep “all” its third party contracts, including the Mt. Sinai contract, in effect. Ex. 5 at § 2.2(h).

control the use of the licensed Sealfon tool.” Opp’n at 20. But despite Mt. Sinai’s claims, the contract does not give AbbVie the power to force Neurocrine to use the Mt. Sinai patents on its behalf. At best, the contract gives AbbVie the power of the purse strings and certain tie-breaking authority when the joint development committee is unable to agree. *See* Exs. 3, 5. But Mt. Sinai points to nothing in the Collaboration Agreement that requires Neurocrine to use its own patent license that is expressly excluded from the Collaboration Agreement in furtherance of the collaboration,¹⁰ nor does Mt. Sinai point to anything in the Mt. Sinai Agreement that suggests that, even had Neurocrine used the Mt. Sinai patents this way, such use would be improper.

Notably, Mt. Sinai cannot point to any case finding an impermissible *de facto* sublicense in a situation like this one. To the contrary, the only two cases Mt. Sinai cites are sham transactions where the licensed product starts with the party that wants the sublicense, is transferred to the other party for no legitimate business reason except to bless the product with the license, and then immediately transferred back. *See Du Pont*, 498 A.2d at 1110; *Cook, Inc. v. Boston Sci. Corp.*, 333 F.3d 742 (7th Cir. 2003). Here, in contrast, the licensed drug-discovery tool is and remains with Neurocrine, who then (according to Mt. Sinai) engages in research using the patent itself and ultimately passes along the unlicensed compounds to a third party for further development.¹¹ There is no transfer of the patented article (i.e., the discovery tool) at all, much less in a “sham” transaction designed to circumvent the license.

¹⁰ To the contrary, neither the Transition Plan nor Development Plan—the only parts of the Collaboration Agreement where Neurocrine was working with AbbVie—relate to drug discovery in any way, further obviating the need for a drug-discovery tool. *See* Ex. 5 at Exs. F, G.

¹¹ *MedImmune v. PDL BioPharma, Inc.*, No. C08-5590, 2011 U.S. Dist. LEXIS 1721 (N.D. Cal. Jan. 7, 2011) is thus squarely on point. There, the court found no *de facto* sublicense even though Abbott could direct MedImmune to use the patents on its behalf because there was “no allegation . . . that Abbott was authorized to make any of the licensed products itself.” *Id.* at *66. Here too, so long as Neurocrine is the only party that actually used the patented drug-discovery tools, it doesn’t matter if it did so at Abbott’s request. On this point, Mt. Sinai responds only that even if AbbVie had to go through Neurocrine to use the drug-discovery tools (which is permissible under *MedImmune*), AbbVie was authorized to work with the Licensed Product and Follow-On Compounds directly. *See* Opp’n at 18–20. But as explained above, the sublicensing restriction extended only to Mt. Sinai’s patented drug-discovery tool, not the Licensed Products, rendering Mt. Sinai’s attempts to evade *MedImmune* by conflating these issues ineffective.

B. Neurocrine Had No Obligation To Provide Mt. Sinai With An Unredacted Copy Of The AbbVie Agreement

No provision in the Mt. Sinai agreement requires Neurocrine to provide Mt. Sinai its contracts with third parties. Nor would such a clause be reasonable, given that such contracts often have confidentiality provisions that prevent them from being shared with non-parties. Instead, Neurocrine is required only to provide “a report describing the development status in the previous year of each Licensed Product(s), in particular the drug development milestones that were achieved.” Ex. 2 at § 3.5. Recognizing no additional obligation exists, Mt. Sinai asks this Court to “impl[y]” an obligation to disclose the Collaboration Agreement. *See* Opp’n at 25. But “a court is not empowered to read into an agreement obligations that are not apparent on its face” and Neurocrine is not guilty of breaching an obligation that does not exist. *Woods v. Boston Sci. Corp.*, No. 06 Civ. 5380, 2006 U.S. Dist. LEXIS 96050, at *44 (S.D.N.Y. Nov. 1, 2006).

C. Mt. Sinai Fails To Allege Any Damages From Neurocrine’s Alleged Failure To Provide Development And Product Reports

Finally, Mt. Sinai’s breach claims based on Neurocrine’s alleged reporting obligations must be dismissed for failure to allege damages. In the Motion, Neurocrine explained that Mt. Sinai’s complaint was deficient because the only damages alleged were as a result of the alleged breach of the sublicensing provision, meaning there were no damages alleged for any of the other breach of contract claims. Mot. at 15–17. In its Opposition, Mt. Sinai repeats the same mistake: rather than explaining any harm or damages resulting from the alleged deficiencies in Neurocrine’s reporting, Mt. Sinai again lumps all of the “repeated breaches” together and then points to the alleged harm flowing exclusively from the improper sublicense. Opp’n at 24. Mt. Sinai’s response proves Neurocrine’s point: Mt. Sinai has not alleged any harm as a result of the allegedly delayed development reports.¹² These claims should also be dismissed.

III. CONCLUSION

Neurocrine respectfully requests that this Court grant its motion to dismiss.

¹² Further, Mt. Sinai relies exclusively on pre-*Iqbal* case law to claim that conclusory allegations of harm suffice to survive a motion to dismiss. *Compare* Opp’n at 24 n.12; *with* Mot. at 15–17.

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